

Applicant: Jack Longley  
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antibody is designated ACK2.

- 1) *cont.*
57. (New) The method of claim 50, wherein the administration is intralesional, intraperitoneal, intramuscular, subcutaneous, intravenous, liposome-mediated delivery, transmucosal, intestinal, topical, nasal, oral, anal, ocular or otic delivery.

REMARKS

Claims 4-6, 12-19, 23-26, 28-31, 33 and 41-45 are pending and under examination in the subject application. Applicant has hereinabove cancelled claims 4-6, 12-19, 23-26, 28-31, 33 and 41-45 without prejudice and added claims 50-57. Accordingly, upon entry of this Amendment, claims 50-57 will be pending and under examination.

Applicant maintains that these amendments to the claims do not raise any issues of new matter, and that new claims 50-57 are fully supported by the specification as originally filed. Accordingly, applicant respectfully requests that this Amendment be entered.

In view of the remarks set forth below, applicant maintains that the Examiner's outstanding rejections have been overcome and respectfully requests that the Examiner reconsider and withdraw same.

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Claimed Invention

This invention provides methods for treating or preventing cutaneous inflammation. These methods comprise administering to a subject an amount of an antibody that binds to kit protein, thereby preventing or treating cutaneous inflammation.

This invention is based on the *surprising discovery* that inhibition of the kinase enzymatic reaction of kit protein *in vivo* with an anti-c-kit antibody (e.g., ACK2) can decrease cutaneous inflammation.

In this application, the success observed in transgenic mice used in the direct therapeutic administration of anti-c-kit antibodies on inflamed skin was not predictable based on results previously generated by *in vitro* systems. Such lack of predictability is based on *in vivo* variables, such as systemic adverse reactions in the subject, efficiency of anti-c-kit antibody binding to kit protein *in vivo*, and variable reactions associated with different inflamed tissue sites. In support of the unpredictability of *in vivo* systems in view of *in vitro* data, applicant respectfully directs the Examiner to Ando, et al., "Effects of Chronic Treatment with the c-kit Ligand, Stem Cell Factor, on Immunoglobulin E-dependent Anaphylaxis in Mice", J. Clin. Invest., 92:1639-1649 (1993), attached hereto as **EXHIBIT A**, and especially to page 1647, column 1, 2nd full paragraph.

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December 12, 2002 Advisory Action and March 6, 2003  
Examiner's Interview

On December 12, 2002, the Examiner issued an Advisory Action stating that applicant's November 18, 2002 Amendment had not overcome the rejections made in the July 16, 2002 Final Office Action.

On March 6, 2003, applicant's undersigned attorney, Alan J. Morrison, Esq. had a telephonic interview with Examiner Ralph Gitomer concerning the Advisory Action. Applicant wishes to thank the Examiner for his time and consideration during the interview.

During the interview, it was agreed that the introduction of claims directed to the subject matter encompassed by new claims 50-57 would further the prosecution of this application. Thus, in order to further prosecution, applicant has added new claims 50-57 and maintains that these claims are patentable. Specifically, applicant maintains that the addition of new claims 50-57 and the cancellation of claims 4-6, 12-19, 23-26, 28-31, 33 and 41-45 obviates the rejection of the cancelled claims under 35 U.S.C. §103 over Columbo and Mohammadi. Likewise, applicant maintains that the addition of new claims 50-57 and the cancellation of claims 4-6, 12-19, 23-26, 28-31, 33 and 41-45 obviates the rejection of the cancelled claims under 35 U.S.C. §112, first paragraph.

Summary

In view of the remarks made herein, applicant maintains that the claims pending in this application are in

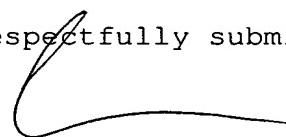
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condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone conference would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the enclosed \$375.00 RCE fee, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

  
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